

## Subpart D—Prosthetic Devices

### § 876.3350 Penile inflatable implant.

(a) *Identification.* A penile inflatable implant is a device that consists of two inflatable cylinders implanted in the penis, connected to a reservoir filled with radiopaque fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. When the cylinders are inflated, they provide rigidity to the penis. This device is used in the treatment of erectile impotence.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before July 11, 2000, for any penile inflatable implant that was in commercial distribution before May 28, 1976, or that has, on or before July 11, 2000, been found to be substantially equivalent to a penile inflatable implant that was in commercial distribution before May 28, 1976. Any other penile inflatable implant shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 65 FR 19658, Apr. 12, 2000]

### § 876.3630 Penile rigidity implant.

(a) *Identification.* A penile rigidity implant is a device that consists of a pair of semi-rigid rods implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction.

(b) *Classification.* Class II. The special control for this device is the FDA guidance entitled “Guidance for the Content of Premarket Notifications for Penile Rigidity Implants.”

[65 FR 4882, Feb. 2, 2000]

### § 876.3750 Testicular prosthesis.

(a) *Identification.* A testicular prosthesis is an implanted device that consists of a solid or gel-filled silicone rub-

ber prosthesis that is implanted surgically to resemble a testicle.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before July 5, 1995, for any testicular prosthesis that was in commercial distribution before May 28, 1976, or that has on or before July 5, 1995, been found to be substantially equivalent to a testicular prosthesis that was in commercial distribution before May 28, 1976. Any other testicular prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 60 FR 17216, Apr. 5, 1995]

## Subpart E—Surgical Devices

### § 876.4020 Fiberoptic light ureteral catheter.

(a) *Identification.* A fiberoptic light ureteral catheter is a device that consists of a fiberoptic bundle that emits light throughout its length and is shaped so that it can be inserted into the ureter to enable the path of the ureter to be seen during lower abdominal or pelvic surgery.

(b) *Classification.* Class II (performance standards).

### § 876.4270 Colostomy rod.

(a) *Identification.* A colostomy rod is a device used during the loop colostomy procedure. A loop of colon is surgically brought out through the abdominal wall and the stiff colostomy rod is placed through the loop temporarily to keep the colon from slipping back through the surgical opening.

(b) *Classification.* Class II (performance standards).

### § 876.4300 Endoscopic electrosurgical unit and accessories.

(a) *Identification.* An endoscopic electrosurgical unit and accessories is a device used to perform electrosurgical procedures through an endoscope. This generic type of device